#### Food and Drug Administration, HHS

#### § 225.135 Work and storage areas.

Work areas and equipment used for the production or storage of medicated feeds or components thereof shall not be used for, and shall be physically separated from, work areas and equipment used for the manufacture and storage of fertilizers, herbicides, insecticides, fungicides, rodenticides, and other pesticides unless such articles are approved for use in the manufacture of animal feed.

# Subpart G—Product Quality Assurance

Source: 51 FR 7390, Mar. 3, 1986, unless otherwise noted.

#### § 225.142 Components.

Adequate procedures shall be established and maintained for the identification, storage, and inventory control (receipt and use) of all Type A medicated articles and Type B medicated feeds intended for use in the manufacture of medicated feeds to aid in assuring the identity, strength, quality, and purity of these drug sources. Packaged Type A medicated articles and Type B medicated feeds shall be stored in designated areas in their original closed containers. Bulk Type A medicated articles and bulk Type B medicated feeds shall be identified and stored in a manner such that their identity, strength, quality, and purity will be maintained. All Type A medicated articles and Type B medicated feeds shall be used in accordance with their labeled mixing directions.

## $\S 225.158$ Laboratory assays.

Where the results of laboratory assays of drug components, including assays by State feed control officials, indicate that the medicated feed is not in accord with the permissible limits specified in this chapter, investigation and corrective action shall be implemented immediately by the firm and such records shall be maintained on the premises for a period of 1 year.

## § 225.165 Equipment cleanout procedures.

Adequate procedures shall be established and used for all equipment used

in the production and distribution of medicated feeds to avoid unsafe contamination of medicated and nonmedicated feeds.

### Subpart H—Labeling

#### § 225.180 Labeling.

Labels shall be received, handled, and stored in a manner that prevents label mixups and assures that the correct labels are used for the medicated feed. All deliveries of medicated feeds, whether bagged or in bulk, shall be adequately labeled to assure that the feed can be properly used.

[51 FR 7390, Mar. 3, 1986]

### Subpart I—Records

## § 225.202 Formula, production, and distribution records.

Records shall be maintained identifying the formulation, date of mixing, and if not for own use, date of shipment. The records shall be adequate to facilitate the recall of specific batches of medicated feed that have been distributed. Such records shall be retained on the premises for 1 year following the date of last distribution.

(Approved by the Office of Management and Budget under control number 0910–0152)

[51 FR 7390, Mar. 3, 1986]

### PART 226—CURRENT GOOD MAN-UFACTURING PRACTICE FOR TYPE A MEDICATED ARTICLES

#### Subpart A—General Provisions

Sec.

226.1 Current good manufacturing practice.

226.10 Personnel.

## Subpart B—Construction and Maintenance of Facilities and Equipment

226.20 Buildings.

226.30 Equipment.

#### Subpart C—Product Quality Control

226.40 Production and control procedures.

226.42 Components.

226.58 Laboratory controls.

## Subpart D—Packaging and Labeling

226.80 Packaging and labeling.